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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/033,571

12/27/2001

Shuyuan Zhang

29853/37702

9714

7590

05/02/2006

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EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/033,571

**Applicant(s)**

ZHANG ET AL.

**Examiner**

Mary E. Mosher, Ph.D.

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/7/05, 2/13/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 70-72 and 74-128 is/are pending in the application.
- 4a) Of the above claim(s) 99-128 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70,72 and 75-97 is/are rejected.
- 7) ☒ Claim(s) 71,74 and 98 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/3/2004 & 5/10/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/7/2005 has been entered.

### ***Election/Restrictions***

Claims 99-128 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/23/2004.

### ***Claim Rejections - 35 USC § 112***

Claims 88-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 88-90 are confusing in stating that the composition is replication incompetent, or is lacking a gene region. Should the claims say that the adenovirus in the purified adenovirus composition is replication incompetent, etc? For claim 91, since it deals with replication complementing host cells, should it depend from claim 88 instead of claim 70?

### ***Claim Rejections - 35 USC § 103***

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On reconsideration, claims 70, 72, 75-77, 80-97 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shabram et al 5,837,520 in view of Perrin et al (Vaccine 13(13):1244-1250, 1995), Garnier et al (Cytotechnology 15:145-155, 1994), and/or Nadeau et al (Biotechnology and Bioengineering 51:613-623, 1996), for reasons of record.

Applicant has amended the claims to require that the claimed method produce a composition with less than 0.8 ng/ml of contaminating nucleic acids. This amount, 0.8 ng/ml, is the amount of contaminating DNA present in a CsCl-purified composition, see page 93 of applicant's specification. In the first Office action, it was pointed out that Shabram teaches products with the 260/280 ratios recited in claims 75-76, indicating the same ratio of nucleic acids to protein in the final composition, and that Shabram teaches products that appear to be at least as pure as CsCl-purified virus. Therefore, there is reason to believe that the purification method of Shabram is able to produce material of the purity recited in the claims. The secondary references provide the growth conditions which are different from Shabram, and motivation to choose different the growth conditions is found either in the references themselves or in the ordinary skill of the art. On full consideration of the amendment (in contrast to what was noted in the interview of 10/6/2005), it is noted that the amount of contaminating DNA in the amended claims is not actually comparable to the amount recited in the claims of patent 6726907. The patent claims recite >400 pg contaminating nucleic acid per  $10^{10}$  pfu of virus, versus >800 pg/ml at any concentration of virus in the application claims. Claims 95-96 do not remedy this difference; they specify the pfu/dose but not the volume of the

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dose. Therefore, the examiner's comments in the 10/6/2005 interview summary appear to have been mistaken, and the examiner apologizes for the mistake.

Claims 78, 79 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shabram et al in view of Perrin et al, Garner et al, and/or Nadeau et al as applied to claims 70, 72, 75-77, 80-97 above, and further in view of Morris et al (Williamsburg BioProcessing Conference, Nov. 18-21, 1996) or Gilbert (Williamsburg BioProcessing Conference, Nov. 18-21, 1996), for reasons of record.

### ***Claim Objections***

Applicant is advised that should claim 75 be found allowable, claim 79 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Allowable Subject Matter***

Claims 71, 74, 98 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/28/06



**MARY E. MOSHER, PH.D.**  
**PRIMARY EXAMINER**